

Steroid injections for shoulder disorders: a systematic review of randomized clinical trials

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SUMMARY

Background. Patients with shoulder disorders are believed to benefit considerably from steroid injections. However, the controversy about their efficacy persists.

Aim. The study was designed to assess the efficacy of steroid injections for shoulder disorders.

Method. A systematic computerized literature search in Medline (Index Medicus 1/1966–10/1995) and Embase (Excerpta Medica 1/1984–10/1995) was conducted, supplemented with citation tracking of all relevant publications. Studies published before November 1995 were selected if steroid injections were randomly allocated to patients with shoulder disorders and when clinically relevant outcome measures were reported. Because the validity of study outcomes depends heavily on the strength of methodological quality, the methods were assessed systematically by two 'blinded' independent reviewers. This resulted in a method score (maximum 100 points) that was based on four categories: study population, interventions, measurement of effect, and data presentation and analysis. Confidence intervals for the differences between groups in success rates were calculated in order to summarize the efficacy of steroid injections.

Results. Only three out of the 16 studies scored more than 50 points, indicating a generally poor quality of methods. Most studies reported small sample sizes. The flaws most often found were incomparability of co-interventions and poor blinding of therapist. The methods assessment was frequently hampered by incomplete information about randomization, prognostic comparability, compliance, outcome measures included, blinding of patients and blinding of outcome measurement.

Conclusions. The evidence in favour of the efficacy of steroid injections for shoulder disorders is scarce. The methods of most studies appear to be of poor quality. The few studies that appear to be credible do not provide conclusive evidence about which patients at what time in the course of shoulder disorders benefit most from steroid injections.

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Introduction

Shoulder disorders

ABOUT 10% of the population suffer from one or more episodes of shoulder disorders in the course of their life.¹ Pain and stiffness in the deltoid region, which cause limitations of daily activities, are the commonest complaints of these patients. Pain is elicited or aggravated by movement and usually restricts the range of movement. Pain when lying on the impaired shoulder results in problems with sleeping.^{1–3} Most often, these shoulder complaints are caused by periarticular soft tissue impairment.^{3,4} A minority of all complaints originate from neurological or generalized musculoskeletal conditions, neoplasms or referred pain from the neck or from internal organs.⁴ Five per cent of all consultations in general practice relate to shoulder disorders.^{1,5,6} Out of all newly presented episodes, 23% resolve within one month, 51% within 6 months and 59% within one year (Van der Windt, *et al*, submitted for publication).

Injection

Twelve per cent of all patient–physician contacts for shoulder disorders involve local steroid injections.⁷ Steroid injections are commonly used in combination with analgesics, NSAIDs, rest, physical therapy or exercises. In the Netherlands, injection therapy is given in 20% of all episodes of shoulder disorders.⁸ Patients with shoulder disorders are believed to benefit considerably from steroid injections.⁹ However, controversy over their efficacy persists. The anti-inflammatory effects of steroid injections are to relieve pain, improve or maintain joint function, and diminish disability.^{7,10}

The postulated mechanisms for the effects of steroid injections have not been supported by sufficient clinical empirical evidence. Steroid injections should inhibit the synthesis of inflammation-mediating substances (e.g. prostaglandins), stabilize mast cells and inhibit cellular activity; pain-reducing effects have been reported.¹² In addition, a decrease of tissue calcification and iron deposition has been reported, together with increased vascularization, permeability of the synovial membrane and viscosity of synovial fluid.^{7,10–12} Regenerating effects on damaged articular cartilage¹³ or slowing of the progression of cartilage attrition^{7,12} have not been demonstrated.

Adverse clinical effects of steroid injections have not been systematically investigated. Dermal atrophy, bacterial arthritis, haemarthrosis and thrombophlebitis are attributed to technical artefacts,^{7,12,14} while urticaria and facial flushing are ascribed to suspension preservatives.⁷ Charcot arthropathy is reported in about 1% of all injections and systemic post-injection flare (i.e. acute steroid synovitis with fever), paresis and vertigo in about 2% of all injections. Ligamentous laxity, joint instability and calcification or rupture of tendons and joint capsules, caused by collagen necrosis and increased soft tissue degeneration, are associated with depot injections of long-acting steroids and repeated injections to the same joint.^{12,13} Therefore, repeated injections in the same joint within a short period of time should be avoided. Zuckerman *et al* recommend injecting the same joint only once

in every 6 weeks, with a maximum of three times per year.¹³

In this systematic review, we summarize the results of randomized clinical trials (RCTs) on the efficacy of steroid injections for shoulder disorders. While RCTs offer the best possibility for a valid evaluation of treatment efficacy,¹⁵⁻¹⁷ many aspects of design, conduct and analysis require careful handling for conclusions to be valid. In order to minimize bias, we assessed the methods of available trials according to generally accepted methodological requirements for intervention research.¹⁵⁻²⁰

Method

We identified relevant publications by means of computerized searches and citation tracking. The search strategy included Medline (*Index Medicus* 1/1966–11/1995) and Embase (*Excerpta Medica* 1/1984–11/1995). Potentially relevant papers were harvested from a total of 105 records in *Index Medicus* and a total of 101 records in *Excerpta Medica*. In addition, relevant citations of available papers were traced.

For this systematic review, we included studies that met the following conditions:

- Patients had shoulder pain at the moment of inclusion.
- At least one of the treatment regimens included steroid injections.
- Treatment regimens were allocated by a random procedure.
- Clinically relevant outcome measures were included (e.g. treatment success, pain, mobility or functional status).
- Results were published as a full report before November 1995.

GJMGH selected the study reports. In order to minimize potential reviewer bias, he blinded papers for author(s), journal identification, results and conclusions. BWK and JK independently assessed the blinded reports with respect to the quality of study methods. Then, still blinded, they resolved disagreement in a consensus discussion. Our assessment of methods was based on four categories (Table 1): (1) study population; (2) interventions; (3) measurement of effect; and (4) data presentation. We divided these four categories into 15 different criteria (A–O). Similar criteria are used in peer review systems of journals²¹⁻²⁴ and have been used in other systematic reviews.²⁵⁻³³ For this review, we adjusted the criteria for application to steroid injections and shoulder disorders.

For each of the 15 criteria (A–O), we assigned a weight relative to its putative importance for validity, precision or clinical relevance. The information from the papers about each criterion was analysed. If sufficient information was reported, the likelihood of potential bias was evaluated. If bias was unlikely, the criterion was rated as satisfied. For each study, we calculated a method score by summing the weights for all criteria satisfied. The studies were subsequently ranked according to this sumscore. The theoretical maximum sumscore of 100 points could be obtained when the design, conduct and results of a study were adequately reported and bias was considered to be unlikely in all criteria.

Incomplete information about study methods may hamper the assessment of the quality of methods. The sumscore of the weights for insufficiently reported criteria indicates the amount and magnitude of this incomplete information.

Success rates were determined for each intervention group by dividing the number of documented successes at the end of the intervention period by the number of patients randomly allocated to the intervention. These calculations were made according to the intention-to-treat principle; 'drop-outs' and 'loss-to-follow-up' were assumed to represent failures. The differences between

Table 1. Criteria list for a methods assessment of randomized clinical trials of steroid injections for shoulder disorders.

Criteria	Weight
<i>Study population</i>	
A Selection	4
B Adequate randomization procedure	5
C Study size	15
D Comparability of relevant prognosis at baseline	10
E Drop-outs described for each treatment group separately	6
F Loss-to-follow-up described for each treatment group separately	5
<i>Interventions</i>	
G Description of treatment(s)	12
H Co-interventions avoided (or comparable)	4
<i>Measurement of effect</i>	
I Patients blinded	4
J Therapist blinded	4
K Observer blinded	4
L Relevant outcome measures	10
M Blinded outcome measurement	5
N Duration of follow-up	4
<i>Analysis and results</i>	
O Adequate analysis and presentation	8
Total	100
<p>A Two points if target population is defined by means of explicit selection criteria; 2 points if selection is restricted to a population homogenous for relevant prognostic markers (e.g. duration of complaints, painful arc, pain at night, radiating pain and prior treatment).</p> <p>B Five points if number generation and concealed allocation is used for treatment allocation</p> <p>C Five points if smallest group is bigger than 25 patients immediately after randomization; 10 points if more than 50 patients; 15 points if more than 75 patients.</p> <p>D Two points each if study groups are comparable at baseline for: (1) duration of the complaint; (2) baseline scores for outcome measures; (3) age; (4) number of relapses; or (5) radiating pain.</p> <p>E Six points if no patients withdrew after randomization (drop-outs): 2 points if the number of drop-outs is presented for each study group separately; 4 additional points if reasons for withdrawal are specified for each study group separately.</p> <p>F Loss-to-follow-up: 100 minus [the number of patients at the main moment of effect measurement for the main outcome measure (if not stated according to the reviewers), divided by all randomized patients, times 100%]. One point if loss-to-follow-up is less than 20% in each group; 4 points if it is less than 10% in each group.</p> <p>G One point for every adequately described feature of injection and reference treatment: treatment type; steroid type or modality; needle placement or application technique; intensity or solution; treatment number and frequency; compliance. Two additional points if both placebo and pragmatic control group are included.</p> <p>H One point if co-interventions are comparable between the groups; 3 points if co-interventions are standardized or avoided in study design.</p> <p>I Two points if blinding of patients was attempted or only naive patients were enrolled; 2 additional points if blinding for treatment contrast proved successful.</p> <p>J Two points if blinding of therapists was attempted; 2 additional points if blinding for treatment contrast proved successful.</p> <p>K Two points if blinding of observer was attempted; 2 additional points if blinding for treatment contrast proved successful.</p> <p>L Two points for every assessed outcome measure: (1) pain; (2) success rate or proportion for global measure of improvement or recovery; (3) functional status (activities of daily living); (4) mobility (range of motion); and (5) medical consumption (e.g. medication or surgery).</p> <p>M One point for every blindly assessed outcome measure (see L)</p> <p>N Two points if outcomes were assessed immediately after the last treatment; 2 additional points if this was done 3 months or longer after randomization.</p> <p>O Five points if data for most important outcome measure on the most important moment of effect measurement are adequately presented (frequencies or mean, and standard deviation or centiles); 3 additional points for an adequate analysis, with adjustment for drop-outs, loss-to-follow-up, missing values, non-compliance and co-interventions if appropriate.</p>	

Table 2. Results of the methods assessment of the randomized clinical trials of steroid injections for shoulder disorders.

First author	A 4	B 5	C 15	D 10	E 6	F 5	G 12	H 4	I 4	J 4	K 4	L 10	M 5	N 4	O 8	Method score	Information incomplete
Petri ³⁹	2	5	5	2	-	5	12	-	2	2	2	8	4	2	8	59	26
Adebajo ⁴⁰	4	-	-	6	6	5	12	-	2	-	2	6	3	2	8	56	16
Vecchio ⁴¹	4	-	5	6	6	5	10	3	2	-	-	6	-	2	5	54	36
De Jong ⁴²	2	5	-	6	6	1	8	3	2	2	2	6	2	2	-	47	31
Richardson ⁴³	2	-	5	6	2	1	8	3	2	-	2	4	2	2	5	44	37
White ⁴⁴	4	-	-	8	2	-	8	-	2	-	2	6	2	2	5	41	45
Withrington ⁴⁵	-	-	-	4	6	5	8	3	2	-	2	4	2	2	3	41	34
Jonquière ⁴⁶	4	5	10	4	2	-	8	-	-	-	2	6	-	4	5	40	44
Jacobs ⁴⁷	2	-	-	4	6	1	8	-	-	-	2	6	-	4	5	38	35
Berry ⁴⁸	2	-	-	2	6	5	6	-	-	-	2	6	1	2	5	37	29
Rizk ⁵⁰	4	-	-	6	2	1	8	3	-	-	2	4	1	4	-	35	40
Hollingworth ⁵¹	2	-	5	2	-	-	8	-	2	-	2	2	1	2	5	31	53
Knorre ⁵²	-	-	5	4	-	-	8	-	-	-	-	4	-	2	5	28	47
Dacre ⁵³	4	-	-	4	-	1	2	-	-	-	2	4	1	4	-	22	49
Bulgen ⁵⁴	4	-	-	-	-	-	6	-	-	-	2	4	-	4	-	20	57
Lee ⁵⁵	2	-	-	-	-	-	4	-	-	-	-	2	-	2	-	10	51

the success rates and the corresponding 95% confidence intervals (95% CIs) were calculated for all relevant comparisons.

Results

Methodological quality

We identified 22 papers reporting studies that met our five conditions for inclusion in the blinded method assessment. We excluded five studies: one³⁴ because it was only published as an abstract; one³⁵ because the results of patients who received injection could not be identified separately; and three studies³⁶⁻³⁸ without a contrast for injection between intervention groups. The quality of methods of the remaining 16 papers and two theses³⁹⁻⁵⁶ was assessed.

Initial disagreement between the two independent reviewers was found mostly to result from reading errors. All discrepancies were easily resolved during a consensus discussion, the methods scores are based on the reviewers full agreement. For two studies that have been reported more than once,^{48,49,55,56} we calculated the method scores from the combined information. Hence, the results of 16 RCTs are presented.

Table 2 presents, for each study, the points assigned to each criterion and the method score; the main features of the design of the 16 RCTs and their results are given in Table 3.

All studies scored less than 60 points. Only three studies³⁹⁻⁴¹ attained a method score of more than 50 points, indicating the poor overall methodological quality of most studies. In general, studies proved to be methodologically sound with respect to (A) patient selection, (E) reported drop-outs, (G) intervention descriptions, and (O) analysis and presentation of data. Nevertheless, the range of the method score is wide (average 37 points, range 10-59). The most prevalent flaws were in (H) incomparability of co-interventions and (J) poor blinding of therapist. In addition, most study sizes (C) were small.

The sumscores for insufficiently reported criteria varied widely (average 39 points, range 16-57). Methods assessment was often hampered by incomplete information about (B) the randomization procedure, (D) prognostic comparability of study groups at baseline, (G) compliance with interventions, (L) outcome measures and blinding, (I) of patients, (K) of observer, and (M) dur-

ing effect measurement. In addition, reporting of long-term adverse effects was deficient.

Efficacy of steroid injections

Whereas reporting data for treatment success and pain relief generally was informative enough to support the conclusions, several authors drew conclusions about additional outcome measures for which no data were presented. We used differences in proportions of treatment success in order to evaluate efficacy of steroid injections. Poor presentation of data impeded these calculations for five studies.^{42,47,53-55} In only one study⁵⁰ did our intention-to-treat analysis result in slightly different success rates compared with the results reported in the original publication.

In Table 4, the 95% CIs are presented for comparisons between steroid injections and placebo interventions. The studies are ranked according to quality of methods. The two studies^{39,40} with the highest method scores reported a significantly higher success rate for steroid injection (95% CI excludes zero), but in only one study⁴⁰ did the lower limit of the 95% CI exceed a difference in success rate of 20%.

Table 5 shows the 95% CIs for comparisons between steroid injections and competing treatment modalities (mainly physiotherapy or medication). In two out of the three studies with method scores above 50 points,^{39,40} the lower limit of the 95% CI exceeded a 10% difference in success rate in favour of steroid injection. Other studies reporting results in favour of steroid injection^{42,47,51} did not reach a method score of 50 points.

Discussion

Our search strategy in the medical literature identified 16 papers about studies that met our inclusion criteria. It is not very likely that we have missed large RCTs by our rather extensive searches. Nevertheless, additional relevant studies might have remained unpublished or have been published in journals that are difficult to retrieve.

Although the checklist used is not exhaustive, it represents a high standard for quality of methods. Therefore, the maximum score of 100 points is probably not easily reached. However, it is

Table 3. Details of randomized clinical trials of steroid injections for shoulder disorders.

First author for reference	Method score	Diagnostic group symptom duration	Steroid injection (number of patients)	Reference treatment(s) (number of patients)	Reported results*	Authors' conclusion†
Petri ³⁹	59	Painful shoulder ≤ 6 months	i 1 x 40 mg Intrabursal triamcinolone and lidocaine plus placebo naproxen (25) ii 1 x 40 mg Intrabursal triamcinolone and lidocaine plus naproxen 1000mg daily (25)	iii 1 x Intrabursal lidocaine plus placebo naproxen tablets (25) iv 1 x Intrabursal lidocaine plus naproxen 1000 mg daily (25)	Success rates after 2 weeks: (i) 8%, (ii) 20%, (iii) 4%, (iv) 12% Success rates after 4 weeks: (i) 28%, (ii) 28%, (iii) 20%, (iv) 8% Improved pain scores (x±s) after 4 weeks: (i) 2.04±0.31, (ii) 1.95±0.35, (iii) 1.76±0.31, (iv) 1.00±0.32	Significant differences for success rate, pain, ROM and functional status in favour of triamcinolone (i and ii)
Adebajo ⁴⁰	56	Rotator cuff tendinitis ≤ 6 months	i 1 x 80 mg Subacromial triamcinolone hexacetone and lignocaine plus placebo diclofenac (20)	ii 1 x Subacromial lignocaine plus diclofenac 150 mg daily (20) iii 1 x Subacromial lignocaine plus placebo diclofenac (20)	Success rates after 4 weeks: (i) 70%, (ii) 30%, (iii) 0% Improvement pain scores (x±s) after 4 weeks: (i) 4.95±0.74, (ii) 3.60±0.67, (iii) 1.35±0.74	Significant difference for success rate in favour of triamcinolone (i); significant difference for pain ROM, functional status in favour of i and ii.
Vecch ⁴¹	54	Rotator cuff tendinitis ≤ 3 months	i 1 x 40 mg Subacromial methylprednisolone plus lignocaine (28)	ii 1 x Subacromial lignocaine (27)	Success rates after 12 weeks: (i) 32%, (ii) 26% Improvement pain scores (median): after 2 weeks, (i) 10, (ii) 7.5 after 4 weeks, (i) 10, (ii) 8 after 12 weeks, (i) 8, (ii) 8	No significant differences for success rate, pain and ROM
De Jong ⁴²	47	Capsulitis no restriction	i 3 x 40 mg Intra-articular triamcinolone (25) ii 3 x 10 mg Intra-articular triamcinolone (32)		Improvement pain scores (x±s): after 1 week, (i) 22% (ii) 7% after 3 weeks, (i) 40% (ii) 19% after 6 weeks, (i) 54% (ii) 31%	Significant differences for ROM, pain, functional status, sleep disturbance in favour of high-dose triamcinolone (i)
Richardson ⁴³	44	Painful shoulder > 6 months plus distal gic (54)	i 2 x Intra-articular and intrabursal 25 mg prednisolone acetate	ii 2 x Intra-articular and intrabursal saline plus distal gic (47)	Success rates: after 2 weeks, (i) 33%, (ii) 20% after 6 weeks, (i) 53%, (ii) 46%	No significant differences for success rate, ROM and pain
White ⁴⁴	41	Rotator cuff tendinitis no restriction	i 1 x 40 mg Intrabursal triamcinolone acetone plus placebo indomethacin (20)	ii 1 x Intrabursal saline plus indomethacin 100 mg daily (20)	Success rates after 6 weeks: (i) 45%, (ii) 50% Improvement pain scores (x±s) (i) 4.3±5.2, (ii) 5.5±8.3	No significant differences for success rate, pain and ROM
Withrington ⁴⁵	41	Supraspinatus tendinitis ≤ 3 months	i 1 x Supraspinatus tendon 80 mg methylprednisolone and lignocaine (12)	ii 1 x Supraspinatus tendon saline (13)	Success rates: after 2 weeks, (i) 58%, (ii) 31% after 8 weeks, (i) 42%, (ii) 23% Improvement pain scores (x): after 2 weeks, (i) 3.7, (ii) 1.8 after 8 weeks, (i) 2.7, (ii) 1.2	No significant differences for success rate, pain and ROM
Jonquière ⁴⁶	40	Painful shoulder > 6 months	i Cyriax treatment: local triamcinolone, local anaesthesia, physiotherapy (22)	ii Local anaesthesia, physiotherapy (36)	Success rates after 16 weeks: (i) 64%, (ii) 72%	No significant differences for success rate and number of sick leave days

*Reported data for improvement of pain or success rate (ratio of recovered/improved patients to those allocated to respective groups).

†P-values < 5% were considered to be statistically significant; ROM = range of motion.

Table 3. Details of randomized clinical trials of steroid injections for shoulder disorders (continued).

First author for reference	Method score	Diagnostic group symptom duration	Steroid injection (number of patients)	Reference treatment(s) (number of patients)	Reported results*	Authors' conclusion†
Jacobs ⁴⁷	38	Capsulitis no restriction	i 3 x 40 mg Intra-articular triamcinolone (15) ii 3 x 40 mg Intra-articular triamcinolone plus distension (18)	ii Distension only (14)	Improvement of abduction (x±s): (i) 3.4±2.2 (ii) 4.3±2.2 (iii) 1.0±3.8	Significant differences for ROM in favour of i and ii; no significant differences between i and ii.
Berry ⁴⁸	37	Shoulder cuff lesion no restriction	i 1 x 40 mg Intra-articular methyl-prednisolone and lignocaine plus placebo tolmetin sodium (12) ii 1 x 40 mg Intra-articular methyl-prednisolone and lignocaine plus tolmetin sodium 1200 mg daily (12)	iii Acupuncture (12) iv Ultrasound therapy (12) v Placebo ultrasound therapy (12)	Success rates after 4 weeks: (i) 50%, (ii) 42%, (iii) 42%, (iv) 50%, (v) 75% Improvement pain scores (x): (i) 12, (ii) 10, (iii) 7, (iv) 7, (v) 30	No significant differences for success rates, pain and ROM
Rizk ⁵⁰	35	adhesive capsulitis ≤ 3 months	i 3 x 40 mg Intra-articular methyl-prednisolone and lidocaine (16) ii 3 x 40 mg Intrabursal methyl-prednisolone and lidocaine (16)	iii 3 x Intra-articular lidocaine (8) iv 3 x Intrabursal lidocaine (8)	Success rates after 4 weeks: (i+ii) 3% (iii+iv) 12% Improvement pain scores (x): at 4 weeks, (i) 0.1, (ii) 0.4, (iii+iv) 0.7 at 11 weeks, (i) 0.1, (ii) 0.3, (iii+iv) 0.7 at 24 weeks, (i) 0.1, (ii) 0.9, (iii+iv) 1.1	No significant differences for success rate, pain and ROM
Hollingsworth ⁵¹	31	Painful shoulder no restriction	i 40 mg Methylprednisolone functional (39) ii 40 mg Methylprednisolone + lignocaine tender or trigger point injection (38)		Success rates: after 1 week, (i) 60%, (ii) 20% after 2 weeks, (i) 59%, (ii) 19%	Significant difference in favour of group i
Knorre ⁵²	28	Rheumatoid conditions > 6 months	i 1 x 40 mg Intra-articular triamcinolone (30)	ii Ultrasound therapy (30) iii Cryotherapy: icepacks (30)	Perceived benefit 'very good' according to patients: at 2 weeks, (i) 47%, (ii) 50%, (iii) 40% at 12 weeks, (i) 40%, (ii) 50%, (iii) 37%	Pain scores in group i after 12 weeks significantly better than in other groups
Dacre ⁵³	22	Painful stiff shoulder no restriction	i 1 x 20 mg Triamcinolone (22) ii 1 x 20 mg Triamcinolone plus physiotherapy (mainly mobilizations) (20)	iii Physiotherapy only (20)	Only graphical data presentation	No significant differences for pain or ROM
Bulgen ⁵⁴	20	frozen shoulder > 1 month	i 3 x 20 mg Intra-articular plus intrabursal methyl-prednisolone and lignocaine (11)	ii Maitland mobilizations (11) iii Ice packs plus proprioceptive neuromuscular facilitation (12) iv Pendular exercises, analgesics, diazepam (8)	Only graphical data presentation	No significant differences for pain or ROM
Lee ⁵⁵	10	Periarthritis no restriction	i 1 x 25 mg Intra-articular hydrocortisone acetate plus exercise therapy (15) ii 1 x 25 mg Biceps tendon sheath hydrocortisone plus exercise therapy (18)	iii Infra-red irradiation plus exercise therapy (17) iv Analgesics only (15)	Only graphical data presentation	No significant differences, except for less improvement for ROM in group iv

*Reported data for improvement of pain or success rate (ratio of recovered/improved patients to those allocated to respective groups).

†P-values < 5% were considered to be statistically significant; ROM = range of motion.

Table 4. Point estimates and 95% confidence intervals for the difference in success rates in studies comparing steroid injections with placebo treatment for shoulder disorders. The studies are ranked according to methodological quality.

First author	Method score	Comparison	Difference in success rates	95% confidence limits
Petri ³⁹	59	i + ii vs iii + iv	14%	1, 27
Adebajo ⁴⁰	56	i vs iii	70%	50, 90
Vecchio ⁴¹	54		6%	-18, 30
Richardson ⁴³	44		7%	-13, 27
Withrington ⁴⁵	41		27%	-11, 65
Berry ⁴⁸	37	i vs v	-25%	-62, 12
Rizk ⁵⁰	35	i + ii vs iii + iv	-9%	-25, 9

Table 5. Point estimates and 95% confidence intervals for the difference in success rates in studies comparing steroid injections with currently applied treatment modalities for shoulder disorders. The studies are ranked according to methodological quality. Five studies^{42,47,53-55} provided insufficient data for the calculation of confidence intervals.

First author	Method score	Comparison	Difference in success rates	95% confidence limits
Petri ³⁹	59	i vs iv	20%	13, 27
Adebajo ⁴⁰	56	i vs ii	40%	13, 68
White ⁴⁴	41		-5%	-35, 25
Jonquière ⁴⁶	40		-8%	-33, 17
Berry ⁴⁸	37	i vs iii	8%	-32, 48
		i vs iv	0%	-40, 40
		ii vs iii	0%	-40, 40
		ii vs iv	-8%	-48, 32
Hollingworth ⁵¹	31		40%	20, 60
Knorre ⁵²	28	i vs ii	-3%	-28, 22
		i vs iii	7%	-18, 32

disappointing to find that the quality of methods of the published RCTs is so low. This indicates that serious bias was present in most of the available studies. In addition, incomplete information about important features of design and conduct frequently hampered the assessment of the quality of methods. Incomplete information can indicate only poor reporting but may also disguise additional flaws. Guidelines have been proposed to improve the reporting of randomized clinical trials.^{57,58} It is hoped that better reporting of trials will also improve the informativeness of systematic reviews.

Our scoring system provides a quantitative index of the likelihood that the reported results of RCTs are free of bias. However, combining information from different study features in a sum-score for quality of methods may conceal variation between studies, thereby reducing informativeness. Hence, method scores must be interpreted as relative scores, and one must be cautious when comparing the scores between reviews with different research questions.

When the studies are ranked according to their method scores, however, the order of studies included in both our review on NSAIDs²⁶ and the present one does not differ substantially,^{39,40,44,48} despite slightly different criteria and different reviewers. The same holds for studies that were included in both our review about physiotherapy²⁵ and the present one.^{46,48,53-55} Only

one study⁴⁸ was ranked higher in both the other reviews.

The studies included in this review were aimed at a wide variety of conditions and disorders. Unfortunately, there is much confusion and lack of consensus regarding the classification of shoulder disorders. For disorders labelled seemingly straightforwardly as tendinitis or capsulitis, diagnostic criteria differed even between studies. In addition, the majority of the studies included heterogeneous populations with respect to the duration of the shoulder disorders. In order to identify any difference in efficacy of steroid injections between indications, we included diagnostic categories in Table 3; there was no strong evidence for such differences.

A valid randomization procedure, with adequate generation of random number sequence and concealed assignment, can prevent selection bias.⁵⁹ In addition, randomization in blocks can balance sample sizes between treatment groups. Although we excluded studies without random treatment allocation, biased results cannot be ruled out completely, since method assessment revealed that only a few papers gave a clear description of the randomization procedure. Reporting and interpretation of prognostic comparability of groups at baseline was deficient in many studies. An adequate randomization procedure does not always guarantee equal distribution of confounding variables among the study groups, particularly when the study size is small.⁶⁰ Documentation of confounding variables and baseline rates of outcome measures gives some indication of whether the randomization procedure has been successful for these (known and measured) variables. Only occasionally relevant prognostic variables were accounted for, such as recurrence status, prior treatment (e.g. steroid injections), involvement of both shoulders and antecedent trauma.

Blinding can prevent information bias during outcome measurement.⁶¹ In a placebo-controlled study, blinding of both patient and therapist can be ensured when the milky colour of steroid injection fluid is masked by covering the ampoule. However, only a few studies reported on blinding of patients and therapists or blinded effect measurement, or attempts to do so. Clinical evidence on the importance of needling techniques is scarce. Although standardization of injections appeared to be adequate, problems with placement of injections, owing to anatomical variations⁶² or inaccurate intra-articular needling techniques,⁶³ might contribute to poor clinical outcome. Nevertheless, Hollingworth *et al*⁵¹ reported higher success rates for injections directed at the impaired soft tissue structure that was identified during physical assessment compared with tender or trigger-point injection.

Little information was provided about the scales and procedures employed during outcome measurement. Pain and recovery or general improvement were the most frequently reported outcome variables. Few studies provided data about other relevant outcome measures, such as range of motion, functional status and medical consumption. Moreover, although the statistical significance of results was always reported, the statistical tests on which the conclusions were based were reported only occasionally. Little attention was given to the clinical relevance of the results.⁶⁴ Different authors claim positive short-term effects of triamcinolone injection. However, no long-term effects have been reported. In addition, because the generally very short follow-up impeded detection of more serious long-term adverse effects, a valid benefit-risk estimation is not possible. Hence, its effect on long-term prognosis remains unclear.

Although reporting of confidence intervals⁶⁵ was deficient in most studies, only a few studies failed to provide sufficient data about pain and recovery essential for our calculations of 95% CIs. A sufficiently large study size is necessary in order to detect

clinically relevant differences in outcome between interventions. Most confidence intervals proved to be wide owing to small study sizes. Statistical pooling can increase power, but we decided not to pool the data because of the widely varying quality of study methods and inadequate reporting. Pooling was further impeded by the heterogeneity of the studies included with respect to populations, interventions, outcome measures and duration of follow-up. For these reasons, and because of our fear that statistical pooling would yield a biased effect estimate, we preferred systematic methods assessment to study the evidence and to identify and present sources of disparity and conflict among clinical trials.

The evidence in favour of the efficacy of steroid injections for shoulder disorders is scant. Only a few of the available RCTs appear to be credible, but they do not provide conclusive evidence about the efficacy and safety of steroid injections for shoulder disorders, especially regarding long-term outcome. Because of the poor quality of methods of most available studies, it is not possible to formulate a strong and valid judgement for or against the use of steroid injections for shoulder disorders.

There is more evidence for the short-term efficacy of periarticular triamcinolone injection^{39,40} than for prednisolone injection. Future studies into the efficacy of steroid injection should focus on the comparison of periarticular triamcinolone injection with no intervention or a placebo injection. In addition, studies comparing steroid injections with competing treatment modalities should focus on long-term (cost-) effectiveness and benefit-risk ratios. Methodological flaws presented in this review should be avoided. During the design and conduct of studies, more attention should be given to recruitment of a sufficient sample size, a valid randomization procedure, determination of prognostic comparability at baseline, compliance with interventions, restriction or standardization of co-interventions, blinding of therapists, patients and effect measurement, sufficient duration of follow-up, and documentation of adverse effects. In addition, more attention should be given to adequate reporting of design, conduct and results of such studies.

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